

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>
<b>THIS DOCUMENT RELATES TO: WAVE 1 CASES ON ATTACHED EXHIBIT A</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION  
TO EXCLUDE CERTAIN OPINIONS OF DR. STANLEY ZASLAU**

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiffs respectfully request that the Court exclude certain opinions and testimony of Defendants' Urology and Femal Pelvic Medicine and Reconstructive Surgery expert, Stanley Zaslau, M.D., MBA, FACS ("Dr. Zaslau"). In support of their Motion, Plaintiffs state as follows:

**INTRODUCTION**

Dr. Zaslau is board certified in Urology and certified in the subspecialty of Female Pelvic Medicine and Reconstructive Surgery. Exhibit B, Zaslau Report, p. 3.<sup>1</sup> Plaintiffs do not challenge his qualifications as such. However, Dr. Zaslau seeks to offer testimony that is not helpful for the jury, clearly exceeds the bounds of his qualifications, and is founded on insufficient facts and unreliable methodology.<sup>2</sup> Specifically, this Court should exclude Dr. Zaslau's opinions regarding: (1) particle loss and fraying of mechanical-cut mesh; (2) roping or

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<sup>1</sup> As a practical matter, Plaintiffs attach Dr. Zaslau's report from a single case, *Hendrix v. Ethicon Inc.*, et al, 2:12-cv-00595, and cite to Dr. Zaslau's opinions from that report herein. It is Plaintiff's position that the opinions discussed in this Memorandum should be excluded from all Wave I cases, regardless of the plaintiffs or products at issue.

<sup>2</sup> See *Phelan v. Synthes*, 35 Fed. Appx. 102, 105 (4th Cir. 2002) (the reasoning or methodology underlying testimony must be scientifically valid and able to be properly applied to the facts in issue.).

curling of mechanical-cut mesh; (3) the degradation of polypropylene or its clinical significance; (4) whether the products at issue are associated with chronic or long term pain; and (5) his conversations with undisclosed women regarding their reasons for requesting the removal of their mesh.

### LEGAL STANDARD

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by “knowledge, skill, experience, training or education.” Fed. R. Evid. 702. The witness’s testimony also must represent “scientific knowledge,” meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) “will help the trier of fact to understand the evidence or to determine a fact in issue,” (2) is “based upon sufficient facts or data,” (3) is “the product of reliable principles and methods” and (4) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. Opinion evidence may be admitted if it “rests on a reliable foundation and is relevant.” *Daubert*, 509 U.S. at 597. In the end, an expert’s testimony is admissible if it “rests on a reliable foundation and is relevant.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

The duty rests with Dr. Zaslau to proffer expert testimony and “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Even if Dr. Zaslau is qualified and his testimony is reliable, “testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *In re Ethicon, Inc., Pelvic Repair*

*Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, his testimony must “fit” the case, and there must be a “valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Id.*

## ARGUMENT

### **I. Dr. Zaslau’s opinion that particle loss or fraying does not occur with mechanical-cut mesh, or that it has no clinical significance, is not reliable**

Dr. Zaslau seeks to testify that he has “not removed degraded particles of mesh or seen grossly altered structure of the knitting of the mesh” in the specimens that he has explanted. Ex. B, Report p. 9, 16. The underlying logic of Dr. Zaslau’s opinion regarding (the absence of) particle loss and mesh fraying in mechanical-cut mesh is essentially: ‘I have not seen it, so it does not happen.’ Dr. Zaslau admits that he did not know the difference between mechanical-cut and laser-cut mesh until taking part in this litigation, and that his opinion is wholly-based upon his proclamation that he has not noticed a difference between the two types of mesh in his personal experience:

Q. And how do you know whether or not you’re using a mechanical-cut versus a laser-cut mesh?

A. Well, I actually didn’t know the difference until these litigation cases have brought this into the world. I’ve had no issues with -- in knowing the difference in either of them, nor do I think it has any clinical relevance.

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Q. Well, Ethicon felt that there was a clinical need for a laser-cut mesh, didn’t it?

A. I don’t know that they -- I know that they have -- that information had been given to them, that, you know, maybe this should be considered, and obviously they did. But it wouldn’t have mattered to me. I’ve not seen a difference or a need for it.

Exhibit C, Zaslau 3/2/16 Dep., 99:1-24.

That is simply not a reliable basis for a biomedical opinion regarding the particle loss or fraying found in mechanical-cut mesh. This Court has previously rejected this sort of “I have not

seen it, therefore it must not happen” logic. Indeed, in ruling on *Daubert* motions in *Tyree*, the Court held that the “[a]bsence of evidence is not evidence of absence,” and refused to allow defendant’s expert to opine that certain events do not occur simply because he had not observed them in his practice.<sup>3</sup> By that same unassailable reasoning, Dr. Zaslau’s claim that, *as far as he knows*, the mesh he has explanted did not experience particle loss of fraying cannot serve as a reliable scientific basis for rendering the opinion that it did not occur. Therefore, this unscientific testimony should be excluded.

Moreover, Dr. Zaslau admits that his opinion is contradicted by the scientific literature and Ethicon’s own internal documents—but to that fact, he simply responds that his opinion “differs,” that even if particle loss does occur it must have no “clinical significance,” and that he has “no other comments”:

Q. And have you ever been told that the TVT mechanical-cut mesh can release -- that there can be particle loss associated with the mechanical-cut mesh?

A. I’ve read that.

Q. And my understanding is you don’t believe that has clinical significance?

A. I don’t think it does.

Q. You would agree with me that you’ve seen reports of that in the literature?

A. Yes.

Q. And you would agree with me, given your hefty reliance list, that you’ve also seen some Ethicon documents on that?

A. Yes.

Q. And you still conclude, even after reviewing those documents and that literature, that there is no clinical relevance to that issue?

A. That’s correct.

Q. And you would agree with me that the particle loss that Ethicon describes, as well as the literature, is from the TVT mesh itself –

Q. -- which is a foreign body?

A. That the particle loss is from the TVT?

Q. Correct. It’s pretty well-accepted, right?

A. Yeah.

Q. I’m not trying to start a disagreement between us. I’m just trying to get through this. And you would agree with me that your opinion differs from other physicians about the clinical relevance of particle loss?

A. **It differs.**

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<sup>3</sup> *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 583-85 (S.D. W. Va. 2014)).

Q. In what way?

A. Well, experts believe that this can be a source of pain for patients, and other associated symptoms that are supposedly debilitating and lifelong and very problematic.

Q. And you would agree with me that Ethicon itself concluded, at least in part, that the clinical basis for coming up with the laser-cut mesh was the particle loss associated with the mechanical-cut mesh?

A. That may have been a consideration for them, but --

Q. In fact, you've seen documents that suggest that?

A. Yeah.

Q. And your reliance list. Even you've seen Ethicon documents that suggest that's a clinical basis for changing the laser-cut mesh, right?

A. It very well could be.

Q. I mean, you're not going to disagree with a document that you've seen that says that, right?

Q. Correct?

**A. I have no other comments.**

Ex. C, 104:3-10; 105:3-106:5.

Dr. Zaslau went on to testify that his opinion could not be changed even if he was shown documents establishing the significance of particle loss, and that—based solely on his personal observations—he does not “need to consider” contradictory scientific evidence:

Q. Well, look at the middle of the page. It says, “Particle loss is the reason why TVT wants to use laser-cut mesh to eliminate particle loss (which is critical to quality).” Do you see that?

A. I do.

Q. Do you agree with that statement?

A. I've not seen that as an issue, okay? I've also looked at mesh as it comes out of the package from the very beginning. I've not seen any – even any threads that are lost off of any mesh over the years as we take it out and check its expiration date and other opinion of it. So to me, I don't see any difference between laser-cut and mechanical-cut mesh.

Q. Have you seen any studies that conclude otherwise?

A. No.

Q. You haven't?

A. No.

Q. Have you seen any documents where the – one of the co-inventors of the TVT product believes that they won't use laser-cut mesh?

A. No.

Q. You haven't seen that?

A. No.

Q. Wouldn't that affect your opinion?

A. No.

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Q. So -- okay. So fair enough. You just don't consider Ethicon documents in that regard one way or another to support your opinion?

A. These have no effect on my opinion whatsoever.

Q. And you're just -- in other words, you just, because of your own experience, you're just not going to consider them?

A. I don't have -- no.

**A. I don't need to consider them.**

Ex. C. 137:5-138:8; 140:3.

As this Court held in *Sanchez*: “[a]n expert’s opinion may be unreliable if he fails to account for contrary scientific literature and instead ‘selectively [chooses] his support from the scientific landscape.’ ‘[I]f the relevant scientific literature contains evidence tending to refute the expert’s theory and the expert does not acknowledge or account for that evidence, the expert’s opinion is unreliable.’”<sup>4</sup>

Moreover, this type of “no it’s not” *ipse dixit* testimony is not helpful to the jury—because it provides no scientific basis upon which the jury could rely.<sup>5</sup> Neither *Daubert* nor the Federal Rules of Evidence require the admission of opinion evidence that is merely *ipse dixit* of the expert, and a court may conclude that there is too large of an analytical gap between the data and the opinion proffered.<sup>6</sup> That is precisely the case here.

## **II. Dr. Zaslau’s opinion that mechanical-cut mesh does not rope or curl—so long as it is implanted using the accompanying sheath—is equally unreliable**

Similar to his opinion regarding particle loss, Dr. Zaslau’s opinion that mechanical-cut mesh will not rope or curl when properly implanted using the accompanying plastic sheath is based solely on his own observations, which are admittedly contradicted by the scientific

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<sup>4</sup> *Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 U.S. Dist. LEXIS 137189, \*70 (S.D. W. Va. Sept. 29, 2014) (citations omitted).

<sup>5</sup> *Ipse dixit* is defined as “[h]e himself said it; a bare, assertion resting on the authority of an individual.” See Black’s Law Dictionary 828 (6th ed. 1990); see also *Sadow-Pajewski v. Busch Entertainment Corp.*, 55 F. Supp. 2d 422, 427 (E.D.Va. 1999).

<sup>6</sup> *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

evidence. And when asked for support for his observations, Dr. Zaslau said that we would just have to “take his word for it”:

Q. Has anyone ever told you that the TVT mechanical-cut mesh can rope?

A. Yes, I’ve heard that.

Q. From who?

A. From review of the literature.

Q. Have you ever observed that?

A. Yes.

Q. When?

A. When we do different experiments with the mesh ex vivo. So when we pull on the mesh by itself, be it mechanically-cut or laser-cut, it’ll rip and tear, and it won’t regain its normal form. And the pore size will certainly be distorted. But, interestingly, when we do the same thing with the plastic sheath over it, we can’t move the mesh despite how hard we pull. We’ve actually even looked with an operative telescope at patients that we finished doing the TVT on to see if there any evidence of fiber loss or any change in what I think the mesh should look like, and I’ve never seen any.

Q. Have you published the results of that testing?

A. We did not.

Q. Where’s the data to back up that claim?

A. It’s personal experience and just bedside teaching.

Q. So I just have to take your word for it?

A. That’s correct.

Ex. C, 102:1-103:5.

Dr. Zaslau’s opinion on whether mesh ropes or curls is nothing more than the same sort of inadmissible “I have not seen it” testimony that he offers regarding particle loss.<sup>7</sup> He admits that his observations cannot be confirmed, and his opinion cannot be contradicted or tested. It is the sort of opinion that *Daubert* was intended to preclude.

### **III. Dr. Zaslau should be precluded from testifying that polypropylene does not degrade *in vivo***

Dr. Zaslau seeks to offer the opinion that he has not removed “degraded particles of mesh” (Ex. B, p. 9), and that he does not “believe that [polypropylene mesh] can have any

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<sup>7</sup> *Tyree*, 54 F. Supp. 3d at 583-85.

significant degradation” or that degradation has any “clinical relevance.” Ex. C, 125:15-126:14. Dr. Zaslau’s opinions regarding the degradation of polypropylene mesh should be excluded.

As an initial matter, Dr. Zaslau’s lack of knowledge about the degradation process, and the chemical properties of Prolene, should serve to preclude his so called “expert” opinions on the issue. For example, Dr. Zaslau could not definitively explain the degradation process from a chemical prospective—and admitted that his opinion is contradicted by the peer reviewed scientific literature. Ex. C, 130:20-131:19. Likewise, Dr. Zaslau does not know what additives are used in the manufacture of the polypropylene used to make Prolene mesh. Ex. C, 128:23-129:1.

Moreover, Dr. Zaslau did not review necessary and relevant documents regarding degradation—including Ethicon’s own internal documents—and instead, he just insists that polypropylene mesh does not degrade:

Q. Have you seen any documents concluding that mesh degrades?

A. No.

Q. So you haven’t seen any internal Ethicon documents indicating that mesh degrades?

A. No.

Q. Did you ask for any?

A. No.

Q. Why not?

A. **Because it doesn’t degrade.**

Q. So you disagree with Ethicon?

A. I do.

Ex. C, 124:16-125:3; *see also* 126:15-24; 127:21-24. Dr. Zaslau chooses to ignore the relevant evidence,<sup>8</sup> and instead, just blindly asserts that if degradation was clinically significant, Ethicon would have let physicians know. Ex. C, 160:20-23 (“I know that if there were anything pertinent, internally, regarding this procedure that Ethicon would have let physicians know

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<sup>8</sup> *See Sanchez*, 2014 U.S. Dist. LEXIS 137189, \*70.



immediately.”). However, an expert’s testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation.<sup>9</sup>

Dr. Zaslau also testified that he does not test the mesh he explants from patients, so any claim that his degradation opinion is based upon personal experience should be rejected as scientifically unsound. Ex. C, 96:22-97:2. Similar to the opinions discussed above, Dr. Zaslau’s opinion that degradation does not occur, or that if it does it is not “clinically relevant,” should be excluded because it is neither supported by his review and understanding of the scientific material, nor is it based upon scientifically reliable clinical experience

**IV. Dr. Zaslau’s opinion that the TVT is not associated with chronic or long term pain is completely unsupported, and therefore, unreliable**

Dr. Zaslau testified that “[v]ery few people who have had a carefully-implanted device will have *long-term* pain.” Ex. C, 72:10-12. But when asked to provide *any* support in the scientific literature for that opinion, Dr. Zaslau could not do so:

Q. Okay. But I didn’t ask about erosions or extrusions. I asked you to name one study that tracked chronic long-term pain associated with the TVT.

A. I can’t name one.

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THE WITNESS: I can’t think of or see one that specifically refers to that for the long-term.

Ex. C, 72:22-73:20; *see also* 74:5-75:19. Again, Dr. Zaslau’s opinions amount to nothing more than the type of “unsupported speculation” that must be excluded under *Daubert*.<sup>10</sup>

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<sup>9</sup> *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, \*3 (4th Cir., Sept. 8, 1997); *see also* *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

<sup>10</sup> *Brown*, 1997 U.S. App. LEXIS 23559 at \*3 (the expert’s testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); *see also* *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

**V. Dr. Zaslau’s testimony regarding reasons other women may want their mesh removed should be excluded under Rule 403**

During his deposition, Dr. Zaslau offered vague, anecdotal testimony that women request that he remove their transvaginal mesh device because it “was recalled” or “is bad for you,” that women are being “cold-called” about their device, and that this is a product of the society in which we live. Ex. C, 61:9-62:3. These opinions were not disclosed in his Report, and he did not provide any details about these alleged discussions. But even if this opinion was disclosed and properly supported (which it is not), it has no probative value, is severely prejudicial, and should be excluded under Fed. R. Evid. 403. Indeed, this Court previously excluded similar opinions—that women have mesh removed for “legal purposes”—in *Huskey* on the grounds that they were “clearly unreliable and unhelpful.”<sup>11</sup>

**CONCLUSION**

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Dr. Zaslau is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering the lack of experience, knowledge, and reliability inherent in the opinions discussed above, Ethicon cannot carry this burden and his testimony should be excluded.

Dated: April 21, 016

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<sup>11</sup> *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 733 (S.D. W. Va. 2014).

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**CERTIFICATE OF SERVICE**

I hereby certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

s/ Edward A. Wallace